Special 510(k) Summary

A) Manufacturer: Renovis Surgical Technologies, LLC
1901 W. Lugonia Avenue, Suite 340
Redlands, California
92374 USA
Telephone: 909- 557-2360
Fax: 909- 307-8571
Contact: Anthony De Benedictis

Consultant: MEDicept, Inc.
200 Homer Ave
Ashland, MA 01721
Telephone: 508-231-8824
Fax: 508-231-8861
Contact: F. David Rothkopf

B) Device Name: Screw, Fixation, Bone
Washer, Bolt Nut

Common Name: Smooth or threaded metallic bone fixation fastener
Single/multiple component metallic bone fixation appliances and accessories

Proprietary Name: Renovis Cannulated Screw System

Device Regulations: 21 CFR 888.3040
21 CFR 888.3030

Class: II

Product Code: HWC
HTN

C) Predicates: K092082 Synergy Cannulated Screw System

D) Device Description:

The Renovis Cannulated Screw System includes cannulated screws and washers, designed to provide secure fixation for various fracture, osteotomy and arthrodesis indications. All screws are cannulated for use over guide pins, allowing for accurate placement. Screws are available in a range of diameters and lengths in partially threaded or fully threaded designs. The system also includes washers to prevent the screw head from pulling through the cortex. The Renovis Cannulated Screw System implants are made from 316L stainless steel.

E) Intended Use:

The Renovis Cannulated Screw System is intended for long and small bone fracture fixation, including: fractures of the tarsals and metatarsals; metatarsal and phalangeal osteotomies; fractures of the carpals and metacarpals; carpal and metacarpal arthrodesis; small fragments of the hand and wrist; ligament fixation as appropriate; sacroiliac joint disruptions; fractures of the distal femur and proximal tibia; intracapsular fractures of the hip; ankle arthrodesis; and pelvis and acetabulum fractures. This system is not indicated for use in the spine.

F) Comparison to Predicate Device(s):

	Renovis Cannulated Screw System	Synergy Cannulated Screw System
510K Number	TBD	K092082
Product code	HWC, HTN	HWC, HTN
Intended Use/ Indication for Use	The Renovis Cannulated Screw System is intended for long and small bone fracture fixation, including: fractures of the tarsals and metatarsals; metatarsal and phalangeal osteotomies; fractures of the carpals and metacarpals; carpal and metacarpal arthrodesis; small fragments of the hand and wrist; ligament fixation as appropriate; sacroiliac joint disruptions; fractures of the distal femur and proximal tibia; intracapsular fractures of the hip; ankle arthrodesis; and pelvis and acetabulum fractures. This system is not indicated for use in the spine.	The Synergy Cannulated Screw System is intended for long and small bone fracture fixation, including: fractures of the tarsals and metatarsals; metatarsal and phalangeal osteotomies; fractures of the carpals and metacarpals; carpal and metacarpal arthrodesis; small fragments of the hand and wrist; ligament fixation as appropriate; sacroiliac joint disruptions; fractures of the distal femur and proximal tibia; intracapsular fractures of the hip; ankle arthrodesis; and pelvis and acetabulum fractures. This system is not indicated for use in the spine.
Material composition	316L stainless steel	23Mn-21Cr-1Mo low nickel stainless steel alloy or Ti-6AL-4V titanium alloy
Performance characteristics	Same design dimensions; same performance	
Sterility	Not provided sterile; sterilize before use; same sterilization directions	
Biocompatible	Yes; known	Yes; known
Comply with	ASTM F -138	ASTM F-2229 or ASTM F-136

Substantial Equivalence Discussion

The Renovis Cannulated Screw System cannulated screws and washers manufactured with 316L stainless steel (316L SS) are substantially equivalent to previously cleared Synergy Cannulated Screw System cannulated screws and washers manufactured with 23Mn-21Cr-1Mo low nickel stainless steel alloy or Ti-6AL-4V titanium alloy. The Renovis Cannulated Screw System manufactured with 316L SS has the following similarities to the predicate device:

- the same intended use
- the same operating principle
- the same design and dimensions
- incorporates similar materials
- the same packaging
- the same sterilization directions
- is biocompatible

Performance

No performance testing is included in this application.

Conformity to Standards

The Renovis Cannulated Screw System conforms to the following standards:

- ASTM 316LVM F-138-00 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants
- ISO 17665-1 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

Conclusion

The only difference between the Renovis Cannulated Screw System and the predicate is the grade of stainless steel manufacturing material. The manufacture of the Renovis Cannulated Screw System with 316L SS does not raise issues of safety or effectiveness, and is therefore substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Renovis Surgical Technologies, LLC
% MEDicept, Inc.
Mr. David F. Rothkopf
200 Homer Avenue
Ashland, Massachusetts 01721

DEC - 9 2011

Re: K113084
Trade/Device Name: Renovis Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: November 7, 2011
Received: November 9, 2011

Dear Mr. Rothkopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113084

Device Name: **Renovis Cannulated Screw System**

Indications for Use:

The Renovis Cannulated Screw System is intended for long and small bone fracture fixation, including: fractures of the tarsals and metatarsals; metatarsal and phalangeal osteotomies; fractures of the carpals and metacarpals; carpal and metacarpal arthrodesis; small fragments of the hand and wrist; ligament fixation as appropriate; sacroiliac joint disruptions; fractures of the distal femur and proximal tibia; intracapsular fractures of the hip; ankle arthrodesis; and pelvis and acetabulum fractures. This system is not indicated for use in the spine.

Prescription Use X 21CFR 801, Subpart D **OR** Over-the-Counter Use _ 21 CFR 876.1500

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign Off
Office of Device Evaluation

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113084

510 (K) _____